

### **REMARKS**

Applicants have carefully reviewed the Office Action of March 23, 2009, in which claims 1 and 4-27 are pending and have been rejected. No amendments have been made with this response.

#### ***Claim Rejections under 35 U.S.C. § 103***

Claims 1, 4, 6-8 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barbere (U.S. Patent No. 6,066,157) in view of Barath (U.S. Patent No. 5,616,149) and Adams et al., U.S. Patent No. 5,941,871. Applicants respectfully traverse the rejection.

The Office Action states “it would have been obvious to one of ordinary skill in the art at the time of [sic] the invention was made to make the construction design as taught by Barath, since Barath states at column 2, lines 15-16 and 45-48 that such modification would cause less damage to blood vessels.” Applicants disagree that these passages provide reasons to modify Barbere in view of Barath.

Barath states, at column 2, lines 12-16 that “Other techniques to recanalize diseased vessels or make incisions in a vessel wall have been described, but those that remove the bulk of the atherosclerotic lesion actually provoke more extended injury in the vessel and result in a higher reparative/proliferative response than with balloon angioplasty.” Barbere teaches balloon angioplasty devices and techniques. Barath is teaching its device is an improvement over atherectomy devices and techniques “that remove the bulk of the atherosclerotic lesion.” Barath does not state that its device would cause less damage to blood vessels than angioplasty, and thus this statement cannot be a reason to modify the angioplasty devices of Barbere in view of Barath.

At column 2, lines 45-48 Barath teaches that its invention provides a means for “facilitating balloon angioplasty procedures.” How, then, does the device of Barath facilitate balloon angioplasty procedures? Barath teaches “The device is then actuated so that the cutting edges penetrate and make cuts into the vessel. A conventional balloon catheter is then moved into the previously cut vessel and inflated so as to dilate the vessel.” Column 6, lines 16-18. The device of Barath is not a replacement for or an improvement on a conventional balloon angioplasty device; rather, it is a supplement to a conventional balloon angioplasty device. Thus, while these lines of Barath may provide motivation for modifying a conventional balloon

angioplasty procedure, they provide no motivation for modifying a conventional balloon angioplasty device.

Adams et al. are cited for teaching longitudinally aligned lumens 66, and it is argued that "It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of openings, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art."

However, what is claimed is not merely a plurality of openings (which all the references teach) but a plurality of distal openings arranged about the outer tubular member in one or more longitudinally aligned sets. Adams et al. teach this. But modifying Barbere in view of Barath in view of Adams et al. to include such a plurality of openings is not a mere duplication of parts. Barbere is directed to an anchor joint for coaxial balloon dilation catheter, which permits distal movement of the inner tube with respect to the outer tube while precluding proximal movement of the inner tube with respect to the outer tube. Barbere, abstract. Part of the solution of Barbere involves a relatively short section of the inflation lumen protruding into the balloon inflation cavity, as shown in Figure 3a. One cannot modify Barbere to include an inflation lumen that extends through the length of the balloon, as in Barath, without changing the principles of operation of Barbere. Therefore one has a relatively short length in which to place the distal openings. One cannot place longitudinal aligned openings in such a space without some compromise – either too little material between the openings or openings whose reduced size would limit the rate of inflation or deflation. Thus the modification of Barbere in view of Barath in view of Adams et al. does not involve mere duplication of elements. Moreover, since the openings could not be placed under the one or more cutting members, there seems to be no reason or advantage to include such a feature.

For at least the reasons discussed above, Applicants submit that no *prima facie* case of obviousness has been made over the cited art with respect to claim 1. As such, Applicants believe claim 1 to be in condition for allowance. As claim 4 depends from claim 1 and contains additional elements, Applicants submit that this claim is likewise in condition for allowance. Independent claim 6, which contains similar elements, is believed to be in condition for allowance for similar reasons. Claims 7-8 and 10 are also believed to be in condition for allowance, as they depend from claim 6 and contain additional elements.

Further, with respect to claim 10, Barbere does not disclose an inflation lumen positioned radially from a guidewire lumen. Because the inflation lumen and the guidewire lumen of Barbere are concentric, there is no radial difference in their position; they both are centered on the central longitudinal axis of the device.

Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Barath and Barbere as applied to claim 1 above and further in view of Saab, U.S. Patent Pub. No. 2006/0106336. Applicants respectfully traverse the rejection.

As discussed above, one cannot modify Barbere, in which the distal end of the inner tube terminates within the balloon inflation cavity, to include an inflation lumen that extends the length of the balloon, as in Barath, without changing the principles of operation of Barbere, for which such a construction is essential. To align the distal ends of the inner and outer tubes of Barbere would likewise violate the principles of operation of Barbere. For at least this reason, therefore, Applicants submit that there is no motivation to combine the references as suggested. For at least this reason, and because claim 5 depends from claim 1, which Applicants submit is allowable, and contains additional elements, Applicants submit that claim 5 is also in condition for allowance.

Claims 9 and 11-13 were rejected under 35 U.S.C. §103(a) over Barath, Shaw et al., U.S. Patent No. 7,279,002, and Barbere as applied to claim 7 above and further in view of Saab. Applicants respectfully traverse the rejection.

(Applicants assume the rejection was made over Barath, Shaw et al. and Barbere as applied to claim 5, as no rejection of claim 7 over Shaw has been made, and will proceed accordingly.)

Claim 9, which recites “wherein a distal end of the inner tubular member and a distal end of the outer tubular member are substantially aligned” is submitted to be allowable over this combination of references for the reasons given above with respect to claim 5.

Claim 11 depends from claim 6 which recites “a first set of longitudinally aligned opening defined in the shaft” and “a first cutting member coupled to the balloon and radially aligned with the first set of longitudinally aligned openings.” Saab depicts several embodiments of a multi-lumen catheter with a balloon. In one embodiment, depicted in Figures 1 and 2, the balloon chambers 24, 26 and 28 are thin-walled portions of inflation lumens 12, 14 and 16. A second embodiment, depicted in Figures 3-5, has a single inflation lumen and several perimeter

lumens. A third embodiment is similar to the second embodiment, wherein the perimeter lumen is used to distribute fluid. A fourth embodiment, depicted in Figures 7-9, includes a single main inflation lumen and perimeter lumens that inflate inward to clamp down on an object such as a guidewire within the balloon. A fifth embodiment, depicted in Figures 10-11, has inflation lumens on the perimeter of the balloon such that it is not possible to include a longitudinally aligned set of openings radially aligned with a first cutting member. A sixth embodiment, in Figures 12-14, depicts a perfusion catheter where chambers 134, 135, 136 and 138 are used for perfusion when balloons/lumens 126, 127, 128 and 130 are inflated. None of these embodiments are suitable for creating a catheter having a set of longitudinally aligned openings radially aligned with a cutting member coupled to the balloon as the designs either preclude the possibility of including a longitudinally aligned set of openings or preclude the possibility of aligning such a set of openings with a cutting member.

For at least this reason and for the reason that claim 11 depends from claim 6, which Applicants submit is allowable, and contain additional elements, applicants submit that claim 11 is also in condition for allowance. As claims 12-13 depend from claim 11 and contain additional elements, Applicants likewise submit that these claims are allowable as well.

Claims 14-15 and 21-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barbere. Applicants respectfully traverse the rejection.

(It appears, from the substance of the rejection, that the Barath and Adams et al. references were also used; Applicants will proceed as if this were a rejection over Barbere in view of Barath and Adams et al.)

Independent claim 14 recites "a first side lumen" and a second side lumen" and independent claim 21 recites "a plurality of side lumens." None of the references used in the rejection disclose, nor are alleged to disclose, first and second side lumens or a plurality of side lumens. Therefore, because the proposed modification would not produce the invention of claim 14 or claim 21, Applicants submit that no *prima facie* case of obviousness has been made.

Moreover, if a new rejection were made which included the Saab reference, as in the claim 5 rejection or the claims 9 and 11-13 rejection above, the arguments made above with respect to claim 1 and claim 11 would apply with equal force here. For at least these reasons, Applicants submit that claims 14 and 21 and claims 15 and 22, which depend from one of claims 14 and 21 and contain additional elements, are in condition for allowance.

Claims 16-18 and 23-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barbere as applied to claim 14 and further in view of Saab. Applicants respectfully traverse the rejection.

As discussed above, Saab fails to remedy the defects discussed above in the rejection of independent claims 14 and 21, from which these claims depend. As such, Applicants submit that these claims are in condition for allowance for at least the reason that these claims depend from one of claims 14 and 16, which Applicants submit are in condition for allowance, and contain additional elements.

Claims 19-20 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barbere as applied to claim 14 and further in view of Barath. Applicants respectfully traverse the rejection.

As discussed above, Barath fails to remedy the defects discussed above in the rejection of independent claims 14 and 21, from which these claims depend. As such, Applicants submit that these claims are in condition for allowance for at least the reason that these claims depend from one of claims 14 and 16, which Applicants submit are in condition for allowance, and contain additional elements.

### ***Conclusion***

Reconsideration and further examination are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

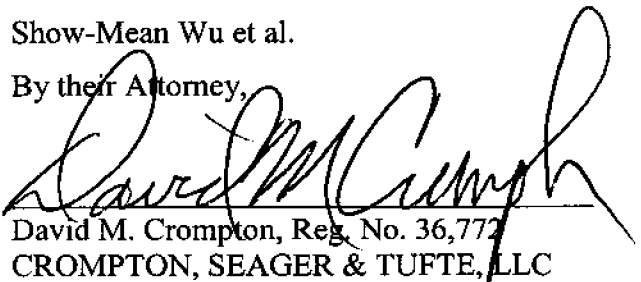
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Respectfully submitted,

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